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Long-term clinical results of biodegradable vascular scaffold ABSORB BVS™ using the PSP-technique in patients with acute coronary syndrome

Evaluation of BVS implantation using PSP-technique in ACS patients

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Abstract

Background: The PSP (predilatation, sizing, post-dilatation)-technique was developed to improve the prognosis of patients after bioresorbable vascular scaffold (BVS) implantation. In acute coronary syndrome (ACS) the use of BVS is particularly demanding and carries some potential risk regarding aggressive lesion preparation, proper vessel sizing due to spasm and thrombus inside the artery. The aim herein, was to determine the long-term results of BVS stenting in ACS patients depending on the scaffold implantation technique.

Methods: The present study is a prospective, two-center study, which consisted of 182 patients who underwent percutaneous coronary intervention (PCI) with BVS (Absorb, Abbott Vascular, Santa Clara, California, USA) implantation for the ACS. All patients were divided into two groups. The first consisted of 52 patients treated with the PSP-technique (PSP group). The second group enrolled 130 patients treated with a non-PSP procedure (non-PSP group).

Results: The procedure was successful in all patients. The mean observation time was 28.8 ± 16.5 months (median 28.3 months, interquartile range 24.0 [17.0–41.0] months). It was found that target vessel failure (TVF) was consistently reduced in patients using the PSP-technique as compared with the non-PSP group (5.8% vs. 17.7%, p = 0.03). Moreover, PSP-technique

was superior to non-PSP-technique concerning major adverse cardiac events (MACE) (3.7% vs. 22.3%, p = 0.02). Logistic regression analysis revealed that the use of PSP technique significantly decreased the risk of target vessel revascularization (odds ratio [OR] 0.11, p = 0.01), TVF (OR 0.28, p = 0.03) and MACE (OR 0.29, p = 0.02).
Conclusions: The PSP-technique for BVS implantation improves long-term results and should also be recommended for newer generations of the bioresorbable scaffold.

Key words: acute coronary syndrome, acute myocardial infarction, STEMI, NSTEMI, angiography, coronary, bioresorbable devices/polymers

Introduction

Bioresorbable vascular scaffolds (BVSs) are a first-generation technology introduced to overcome the limitations of metallic stents [1, 2]. Unfortunately, recent reports of randomized trials revealed several negative results compared with drug eluting stents (DESs) [3–5], especially a higher rate of target-vessel myocardial infarction and scaffold thrombosis [6]. Thick struts of BVS delay endothelialization, correlate with flow disturbance and, in consequence, increase the risk of scaffold thrombosis [7]. Different constructions and mechanical properties make the proper choice of scaffold diameter and its implantation crucial to the results of the procedure. The recent studies have focused on optimal pre-dilatation, sizing of the vessel and post-dilatation to improve treatment results. Ortega-Paz et al. [8] presented the predictive value of PSP (predilatation, sizing, post-dilatation) scores on clinical outcomes. It was an independent predictor of a one-year device-oriented composite endpoint composed of cardiac death, target vessel myocardial infarction, and clinically driven target lesion revascularization. However, the use of BVS and its implantation using PSP-technique in acute coronary syndrome (ACS), the most prothrombotic form of atherosclerosis, is demanding and carries some potential risk regarding aggressive lesion preparation, proper vessel sizing due to spasm and thrombus inside the artery. Moreover, BVS has raised concerns regarding over-expansion, disruption, and the effect of post-dilatation following implantation [9, 10].

Evidence regarding optimal BVS implantation technique in ACS remains limited. These data would be useful in subsequent generations of bioresorbable scaffolds. The aim of

the study is to determine results of BVS stenting in ACS depending on scaffold implantation technique.

Methods

Study design

In this prospective, two-center study, a total of 182 patients were consecutively selected who underwent percutaneous coronary intervention (PCI) with BVS (Absorb, Abbott Vascular, Santa Clara, California, USA) implantation for ACS between December 2012 and October 2015. Eligible patients were hemodynamically stable with left ventricular ejection fraction > 30% and had a life expectancy of at least 5 years. In angiography, they had at least one significant coronary artery stenosis, with no restrictions as to the number, severity or lesion location. Patients were divided into two groups, depending on implantation technique. The first consisted of 52 patients treated with the PSP-technique (PSP group). The second group enrolled 130 patients treated with a non-PSP procedure (non-PSP group). In this group, predilatation was performed in 120 (92.3%) and 17 (13.1%) in post-dilatation patients, respectively.

Patients excluded from the study were with: cardiogenic shock, the life expectancy of less than 1 year. The use of metallic stents during the index procedure and the target vessel reference diameter were < 2.3 mm and > 3.7 mm by visual estimate. Detailed exclusion criteria are presented in Table 3.

Ethics approval was obtained from the Institutional Review Committees in each institution. The study was performed following ethical standards laid down in the 1964 Declaration of Helsinki and its later amendments.

Implantation technique

The PCI procedure was performed according to current PCI guidelines. PSP technique is the recommended optimal implantation method of ABSORB BVS. The definition was derived from the GHOST registry and included three steps: predilatation, proper vessel sizing, and post-dilatation. In PSP group, these implantation criteria were met in all patients. Predilatation was performed using non-compliant (NC) balloon 1:1 ratio with reference vessel diameter (RVD) to obtain optimal lesion preparation. The alternative balloons (scoring or cutting) were considered if NC balloon was not completely expanded. Proper scaffold sizing was based on angiography guidance and online quantitative coronary angiography (QCA)

according to RVD. During implantation, the balloon was inflated slowly with 2 atmospheres every 5 s, maintaining the final pressure for 20 s in the scaffold. Post-dilatation was carried out with an NC balloon > 1:1 ratio with RVD up to 0.5 mm at ≥ 16 atmospheres to confirm the full expansion of the scaffold and optimize overlap zone. In non-PSP group pre- and post-dilatation were at the discretion of the operator, however, were performed according to the principles of PSP technique.

Peri- and post-procedural pharmacotherapy

Each patient naive to antiplatelet therapy, received a loading dose of 300 mg acetylsalicylic acid followed by the maintenance daily dose of 75 mg and one of the following: clopidogrel 600 mg (n = 97; 53.3%), prasugrel 60 mg (n = 1; 0.5%), or ticagrelor 180 mg (n = 84; 46.2%) in loading doses before or immediately after PCI, followed by a maintenance dose of clopidogrel (75 mg *o.d.*), prasugrel (10 mg *o.d.*), or ticagrelor (90 mg twice daily) for a minimum of 12 months. The decision about the continuation of dual antiplatelet therapy (DAPT) after 12 months was made individually for the patient depending on risk of thrombosis. A bolus of unfractionated heparin, 100 U/kg was administered intravenously during the procedure. The remaining pharmacotherapy was applied according to contemporary guidelines.

Data collection

All data were collected in an electronic database. Clinical follow-up was obtained 30 days, 6 months, 1 year and every following year after the procedure by direct contact with patients or telephone interview, and additionally a review of medical reports if the patient had been hospitalized.

Patients were monitored the for the following endpoints: death, myocardial infarction (MI), scaffold thrombosis, target lesion revascularization (TLR), target vessel revascularization (TVR) and target vessel failure (TVF), defined as cardiac death, target vessel MI, and TVR. Additionally, cumulative major adverse cardiac events (MACE) rate, composed of cardiac death, non-fatal infarction or reintervention were analyzed.

Definitions

ST-segment elevation myocardial infarction (STEMI) was defined as an electrocardiographic ST-segment elevation concomitant with characteristic symptoms of myocardial ischemia and subsequent release of biomarkers of myocardial necrosis [11]. New

or presumed new left bundle branch block has been considered a STEMI equivalent. Non-ST-segment elevation myocardial infarction (NSTEMI) definition involved the presence of angina chest pain with a marked elevation of myocardial necrosis biomarkers and no evidence of ST-segment elevation in the electrocardiogram (ECG). Unstable angina was diagnosed in patients with symptoms of myocardial ischemia and no troponin elevation, with or without ECG changes indicative of ischemia (e.g., ST-segment depression or transient elevation or new T wave inversion) [12]. Death was defined as all-cause mortality during the follow-up. Scaffold thrombosis was determined according to the Academic Research Consortium definition [13, 14]. TLR was set as a target segment reintervention including 5 mm proximal and distal to the scaffold.

Revascularization was indicated if symptoms of myocardial ischemia occurred, and positive stress test, electrocardiographic evidence of ischemia at rest, and/or > 70% diameter in-lesion stenosis on angiography were observed. A procedure was angiographically successful with residual diameter stenosis of less than 30% after scaffold implantation in combination with Thrombolysis in Myocardial Infarction (TIMI) III coronary flow. Procedure success was defined as angiographic success in the absence of in-hospital MACE.

Results

The baseline characteristics of the study groups are presented in Table 1. According to these data, clinical presentation and prevalence of cardiovascular risk factors did not differ between groups (for all, $p > 0.05$). In both, middle aged men with hypertension predominated. About one-third of patients suffered from diabetes mellitus. It was noticed that previous MI was significantly more often in the non-PSP group. In turn, the PSP group had more complex lesions, such as higher rate of left main disease, target bifurcation lesion, and significant calcification . There was a significantly higher rate of lesions of type B2/C in the non-PSP group (Table 2).

Total length of the implanted scaffold was significantly higher in the PSP group compared with the non-PSP group (26.8 ± 12.5 mm vs. 22.5 ± 10.3 mm, $p = 0.02$). Quantitative coronary analysis demonstrated a significant more upper reference vessel diameter and lower post-procedural diameter stenosis in patients treated with PSP technique.

Procedural success was obtained in all patients. In three cases coronary dissection occurred and was successfully covered with an additional scaffold. No peri-procedural major

adverse cardiac events were reported. Detailed angiographic characteristics are presented in Table 2.

Complete follow-up was available in 88.5% after 12 months, 83,5% after 24 months, and 63.2% after 36 months. The mean observation time was 28.8 ± 16.5 months (median 28.3 months, interquartile range 24.0 [17.0–41.0] months). The rate of all-cause death and cardiac death was similar in both groups. There was a trend to a higher incidence of MI and TLR in the non-PSP-technique group, however, it was not statistically significant. Scaffold thrombosis occurred only in 1 patient during hospitalization (definite sub-acute thrombosis). No further scaffold thrombosis occurred at follow-up. TVF was consistently reduced in patients using the PSP technique as compared with non-PSP-technique group (5.8% vs. 17.7%, p = 0.03). Moreover, PSP-technique was superior to non-PSP-technique concerning MACE (3.7% vs. 22.3%, p = 0.02).

The logistic regression analysis revealed that use of the PSP technique significantly decreased the risk of TVR (odds ratio [OR] = 0.11, p = 0.01), TVF (OR = 0.28, p = 0.03) and MACE (OR = 0.29, p = 0.02).

Discussion

In this study, it was found that pre-dilatation, proper sizing, and post-dilatation, cold PSP-technique, improve long-term clinical results of bioresorbable absorb scaffolds in patients with ACS. PSP-technique reduces the risk of TVR, TVF, and MACE by almost 8-fold.

Recently, preliminary results for BVS are not very encouraging. The main concerns regard thrombosis and restoration of vessel functionality at long-term follow-up. Data from the randomized ABSORB Japan (2 years), ABSORB III (2 years), ABSORB II (3 years), and AIDA (2-year mean follow-up) trials demonstrated a higher rate of very late scaffold thrombosis with BVS compared to CoCr-EES [3, 4, 15]. Increased strut thickness delays endothelialization and correlates with flow disturbance, increased risk of strut fracture and disruption because of overexpansion [16]. Additionally, BVSs are not as stretchable as metallic stents and cannot be expanded beyond specified limits. Due to these specific properties, implantation of BVS should be performed particularly carefully. PSP technique (precise pre-dilatation and vessel sizing before BVS implantation and post-dilation following implantation) was associated with lower risk of thrombotic events in context with a non-PSP technique [33]. Predilatation and proper vessel sizing increases the rate of successful device

delivery and correct expansion. The data showed that a correct size of the vessel is the most critical determinant of event-free rate during the year subsequent to implantation [20, 21]. The MICAT authors suggested that very-late events could also be associated with a suboptimal sizing of the vessel [19]. In turn, an optimal post-dilation prevents adverse events by maximizing scaffold dimensions, embed struts into plaque, avoid acute malapposition, and reduce shear stress [21].

The PSP technique has been investigated for ABSORB BVS technology [17]. Firstly, it was considered as the five golden "P"s: prepare the lesion, properly size, pay attention to expansion limits, post-dilate with non-compliant balloon as well as pay attention to DAPT [18]. This concept was supported by a group of European experts in a consensus document regarding optimal implantation technique [16] and by results from the MICAT registry (The Coronary Slow-flow and Microvascular Diseases Registry) [19]. In this study, optimal implantation technique significantly reduced the rate of scaffold thrombosis. The post-hoc analysis of the GHOST-EU registry showed a reduction of device-oriented composite endpoint at 1-year follow-up when all three steps of the PSP technique were performed correctly [20].

Moreover, a pooled analysis of the ABSORB trials (ABSORB II, III, CHINA, JAPAN, and EXTEND) revealed that an optimal PSP-technique was strongly associated with clinical outcomes during long-term follow-up [21]. The rationale for the use of BVS in the setting of the ACS are data suggesting that implantation of a temporary scaffold is associated with stabilization of atherosclerotic plaque without a permanent metallic cage. According to recent data, the safety and clinical outcomes of BVS in ACS patients are comparable to that of modern DESs [22]. From a retrospective study, it is also known that scaffold thrombosis can be reduced, when appropriate BVS size, pre- and post-dilatation were employed [23]. In the present study, the rate of scaffold thrombosis was not negligible and occurred in only 1 patient in the non-PSP group who did not have post-dilatation.

Although aggressive lesion preparation improves the rate of successful device delivery, predilatation potentially increases the risk of plaque disruption, thrombus mobilization, and distal embolism [24]. Usually, it is recommended to use semi- or non-compliant balloons with a diameter 0.5 mm smaller or equal to the size of the planned device and characteristics [23]. In the present study, all lesions were pre-dilated in PSP group and 92.3% lesions in non-PSP groups without complications. In all these cases, manual thrombus aspiration was applied before pre-dilatation. The overall procedural success rate was 100%, including all cases with evident thrombus.

Due to the limited expansion and BVS sizes available, vessel sizing is crucial in performing accurate scaffold implantation, especially in patients with ACS. In this group, proper vessel sizing can be limited due to spasm and thrombus inside the artery [25, 26]. Scaffold diameter should be selected according to the reference vessel diameter. The gold standard of correct RVD estimation after proper pre-dilation, and excluded under expansion or malapposition is intravascular imaging [17]. Tanaka et al. [27] reported that patients treated with intravascular imaging guidance, post-dilation balloon/scaffold ratio was higher and final residual percentage stenosis was lower compared with those treated with an angio-guided approach. However, despite the angio- and QCA guided PSP technique has several limitations, such as limited information of the atherosclerotic plaque composition, limited visibility of the scaffold in the angiography, difficulties in the estimation of RVD, and uncertainty of possible scaffold under expansion or malapposition, these techniques are used in the three steps of implantation in most patients. This results from the still limited availability of optical coherence tomography and intravascular ultrasound due to high cost. In the current study the QCA guided approach dominated in the PSP group (65.4%), and angiography-guided approach in non-PSP group (93.2%).

According to the recommended PSP technique, all scaffolds should be post-dilated with NC balloon. However, ACS patients have a potentially increased risk of over-expansion, disruption, and the effect of post-dilatation following its implantation [9, 10]. The ASSURE Registry (21.3% unstable angina) showed that a slight systematic oversizing of BVS, followed by high pressure post-dilatation, is safe and effective [28]. In turn, short-term results of the RAI registry (1,505 patients, 59% ACS) confirmed that high post-dilation rate (96.8%) might mitigate BVS-related events [29]. In a pooled analysis of the BVS Expand and BVS STEMI registries (351 patients, 72.6% ACS), post-dilation in ACS group was only 41.3% [30].

A comparison of BVS vs. everolimus eluting stent (EES) in STEMI patients with a high rate of post-dilation showed favorable mid-term results [31]. In the BVS STEMI first propensity score matching comparisons between 151 BVS patients and 151 EES patients, the MACE rate was higher in the BVS group (9.8% vs. 3.6%, $p = 0.02$, and TLR was 5.7% vs. 1.3%, $p = 0.05$) [32]. Interestingly, the 30-day MACE rate in BVS patients without post-dilatation was 6.8% and 3.6% in patients with post-dilatation. Of note, all BVS cases with acute scaffold thrombosis had no post-dilatation at the index procedure suggesting that optimization of the implantation technique is of paramount importance even in the acute setting. Imori et al. [33] also confirmed the importance of BVS post-dilation in the ACS

setting. At 24 month follow-up, a higher rate of MACE was observed in BVS compared to EES in consecutive ACS patients before and after propensity score matching. However, after sensitivity analysis, MACE rates in BRS patients with post-dilation were significantly lower than in those without post-dilation and were comparable to EES patients (6.0% vs. 12.6% vs. 4.7%, $p < 0.001$). scaffold thrombosis rates were only slightly lower in the BVS group with post-dilatation, but were higher in both BVS groups than in EES patients (2.0% vs. 2.6% vs. 1.2%, $p = 0.09$).

Contrarily to the ABSORB III 2-year results, the investigators did not find any relation between clinical outcomes with either the implantation technique (74% BVS post-dilation rate) or the diameter of the treated vessels or the presenting symptoms. However, among the patients in the scaffold group who had definite or probable device thrombosis, 19% had a residual diameter stenosis of 30% or greater; among the patients who did not have device thrombosis, 9% had a residual percent diameter stenosis of 30% or greater ($p = 0.05$) highlighting the importance to obtain maximal BVS expansion at the end of the procedure. In the present study, post-dilatation was applied in all patients in the PSP group without complications and only in 2 (1.5%) patients in the non-PSP group.

Conclusions

The implantation of BVSs according to the PSP-technique reduced rates of TVR, TVF, as well as MACE, compared with non-PSP-technique implantation during long-term observation. The PSP-technique for BVS implantation improves long-term results and should also be recommended for newer generations of bioresorbable scaffold.

Conflict of interest: Maciej Lesiak has received payments as an individual for the advisory board and speaker honoraria from Abbott Vascular, AstraZeneca, Biotronik, Boston Scientific and Tryton Medical. Stefan Grajek has received payments as an individual on the advisory board and speaker honoraria from Astra-Zeneca, Servier, Pfizer, Sandoz, Adamed, Polpharma. Aleksander Araszkiewicz has received payments as an individual for the advisory board and speaker honoraria from Abbott Vascular. None of the other authors have relationships with Industry to declare.

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Table 1. Baseline clinical characteristics.

Characteristics	PSP-technique	Non-PSP-technique
N	52	130
Male	34 (65.4%)	94 (72.3%)
Age [years]	60 ± 11	58 ± 11
STEMI	7 (13.5%)	22 (16.9%)
NSTEMI	11 (21.2%)	37 (28.5%)
Unstable angina	24 (46.2%)	24 (53.8%)
Cardiovascular risk factors:		
Hypertension	34 (65.4%)	114 (87.7%)
Diabetes mellitus	9 (17.3%)	32 (24.6%)
IDDM	4 (7.7%)	12 (9.2%)
Cardiovascular history:		
Prior MI	14 (26.9%)	24 (18.5%) *
Prior CABG	2 (3.8%)	7 (5.4%)
Prior PCI	13 (25.0%)	35 (26.9%)
Chronic kidney disease	4 (7.7%)	12 (9.2%)

*$p < 0.05$, Mann-Whitney test or t-student test, as appropriate; CABG — coronary artery bypass grafting; MI — myocardial infarction; NSTEMI — non-ST-segment elevation myocardial infarction; PCI — percutaneous coronary intervention; STEMI — ST-segment elevation myocardial infarction

Table 2. Baseline angiography characteristics.

Characteristics	PSP-technique	Non-PSP-technique
Multivessel disease	16 (30.8%)	71 (55.0%)
Target vessel location:		
LM	4 (7.7%)	0 (0.0%) *
LAD	26 (50.0%)	62 (47.7%)
RCA	10 (19.2%)	30 (23.1%)
LCX	8 (15.4%)	22 (16.9%)
Other	4 (7.7%)	16 (12.3%)
Lesion type B2/C	32 (61.5%)	128 (98.5%) *
Calcification	5 (9.6%)	1 (0.8%) *
Bifurcation lesion	14 (26.9%)	14 (10.8%) *
Thrombus	3 (5.8%)	5 (3.8%)
RVD [mm]	3.1 ± 0.4	2.91 ± 0.4
MLD [mm]	0.4 ± 0.2	0.31 ± 0.2
Diameter stenosis [%]	87.3 ± 8.2	88.01 ± 6.7
Qquantitative coronary analysis	34 (65.4%)	9 (6.8%)
Visual estimate	18 (34.6%)	121 (93.2%)
Total number of scaffolds	61	149
Mean scaffolds per lesion	1.17	1.15
Mean scaffold length per lesion	27.2 ± 10.7	22.5 ± 11.1
Mean scaffold diameter per lesion	3.0 ± 0.4	3.0 ± 0.4
Radial approach	50 (96.1%)	125 (96.1%)
Pre-dilatation	52 (100%)	120 (92.3%)
Mean pre-dilatation balloon diameter [mm]	2.9 ± 0.5	2.7 ± 0.5
Maximum pre-dilatation pressure [atm]	13.1 ± 2.3	13.5 ± 1.2
Post-dilatation	52 (100%)	2 (0.5%) *
Mean post-dilatation balloon diameter [mm]	3.1 ± 0.8	3.5 ± 0.0
Max post-dilatation pressure [atm]	17.8 ± 2.4	16.0 **± ????**
Complications occurring any time during the procedure:		
MACE	0 (0.0%)	0 (0.0%)
Dissection	2 (1.5%)	1 (1.9%)
Distal embolism	0 (0.0%)	0 (0.0%)
No-reflow	0 (0.0%)	0 (0.0%)
Angiographic success	52 (100%)	130 (100%)
Procedure success	52 (100%)	130 (100%)

*$p < 0.05$, Mann-Whitney test or t-student test, as appropriate; LAD — left artery descending; LCx — left circumflex artery; LM — left main; MACE — major adverse cardiovascular events; MLD — minimal lumen diameter; RCA — right coronary artery; RVD — reference vessel diameter

Table 3. Exclusion criteria.

Known intolerance to aspirin, heparin, PLLA, everolimus, contrast material
Active bleeding or coagulopathy or patients on chronic anticoagulation therapy
Poor compliance
Severe tortuous, calcified or angulated coronary anatomy of the study vessel
Fibrinolysis prior to percutaneous coronary intervention

Table 4. Results.

Characteristics	**PSP-technique**	**Non-PSP-technique**
All cause death	3 (5.8%)	4 (3.1%)
Cardiac death	2 (3.8%)	2 (1.5%)
Any MI	1 (1.9%)	10 (7.7%)
Target vessel MI	1 (1.9%)	6 (4.6%)
Scaffold thrombosis	0 (0%)	1 (0.8%)
Target lesion revascularization	0 (0%)	7 (5.4%)
Target vessel revascularization	1 (1.9%)	19 (14.6%)*
TVF	3 (5.8%)	23 (17.7%)*
MACE	4 (3.7%)	29 (22.3%)*

*$p < 0.05$, Mann-Whitney test, as appropriate; MACE — major adverse cardiac events; MI — myocardial infarction; TVF — target vessel failure